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| 10/517,759 | 11/04/2005 | Franz Feiner | P0777.70001US00 | 1325 |
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| WOLF GREENFIELD & SACKS, P.C. | | | EXAMINER | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|
| Office Action Summary | Application No. 10/517,759 | Applicant(s) FEINER ET AL. |
| | Examiner CLINTON OSTRUP | Art Unit 3771 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 November 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-19 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 13 December 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-166/08)
 Paper No(s)/Mail Date 11/4/2005
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

1. Claims 1-19 are pending in this application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 1 recites the broad recitation of "a device", and the claim also recites "in particular in an inhalation therapy device" which is the narrower statement of the range/limitation.

Claim 16 recites the broad recitation wherein the "transmitting means is light", and the claim also recites "in particular infrared light" which is the narrower statement of the range/limitation.

Any remaining claims are rejected as depending from a rejected base claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3-4 and 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommer et al. (WO 01/85241A1), based on the machine translation provided by the European Patent Office, and further in view of Danby et al., (5,680,111).

Sommer discloses a nebulizer device (figure 1) for detecting the parameters of an aerosol (flow) comprising a transmitting means (7) which is disposed on a body (5) that at least partially surrounds an aerosol resting area (inside mouthpiece), and which emits radiation (infrared light) into said aerosol resting area through a transparent material; a first receiving means (8), which is disposed on the body (5) that at least partially surrounds said aerosol resting area (inside mouthpiece), which is disposed in relation to said transmitting means (7) so as to primarily receive transmission radiation

(infrared light) , and which emits a first analysis signal (output signal of 8) that corresponds to the intensity of the received transmission radiation; and a control means (9), to which the output signals (via 8) are supplied and which analyses the output signals in order to determine the parameters (flow) of an aerosol in said aerosol resting area. See: figures 1-3 & 12.

However, Sommer lacks the a second receiving means disposed on the body that at least partially surrounds the aerosol resting area; which is disposed in relation to said transmitting means so as to primarily receive scattered radiation and which emits a second analysis signal that corresponds to the intensity of the received scattered radiation.

Danby et al. teaches a device for detecting air in a tubular system that uses a transmitter with two receivers and describes how the system works well with transparent or translucent tubes. Danby teaches how the one receiver is at a ninety degree angle in relation to the transmitter and the other receiver is at a one hundred and eighty degree angle in relation to the transmitter. Danby teaches that both receivers are connected to a processor which processes the light receivers' outputs to detect air in the tubing. See: abstract, col. 3, lines 28-54; col. 4, line 58 - col. 5, line 6 and figures 3 & 8.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the nebulizer flow detection device disclosed by Sommer by utilizing a pair of sensors disposed perpendicular to each other, as taught by Danby, in order to provide a nebulizer flow detector with increased precision.

Regarding the use of a transmitting means which emits radiation into an aerosol resting

area through a translucent material, Danby contemplates using both transparent and translucent materials.

Regarding claim 2, Sommer discloses a transmitting means (7) emits radiation (infrared light) and Danby teaches the first translucent wall section (14 or 15) of the body (5 of Sommer) surrounding the aerosol resting area (inside mouthpiece of Sommer).

Regarding claim 3, the combined references teach a first receiving means (20b of Danby) receives the transmission radiation through a second wall section (adjacent 20b) of the body (5 of Sommer) surrounding the aerosol resting area (inside mouthpiece of Sommer).

Regarding claim 4, the combined references teach a second receiving means (20a of Danby) that receives the scattered radiation (infrared light) through a third wall section (adjacent 20a) of the body (5 of Sommer) surrounding the aerosol resting area (inside mouthpiece of Sommer).

Regarding claim 5, the combined references teach a body (5 of Sommer) surrounding the aerosol resting area (inside mouthpiece of Sommer) and Danby teaches a transparent or translucent material can be used. See: col. 1, line 65 - col. 2, line 13 & abstract of Danby.

Regarding claim 6, the combined references teach a body (5 of Sommer) surrounding the aerosol resting area (inside mouthpiece of Sommer) is made of a transparent material and Danby teaches a transmitting means (21 of Danby), that

functions well whether it is made of a transparent or a translucent material, through which radiation is emitted. See: col. 1, line 65 - col. 2, line 13 & abstract of Danby.

Regarding claim 7, the Danby teaches a first receiving means (20b of Danby) and teaches that the device works reliably well using transparent or translucent materials, thus it would be obvious to provide a surface made of a translucent material, through which the radiation is received because the system provides reliable detection of air bubbles through both transparent and translucent materials.

Regarding claim 8, Danby teaches a second receiving means (20a of Danby) and teaches that the device works reliably well using transparent or translucent materials, thus it would be obvious to provide a surface made of a translucent material, through which the radiation is received because the system provides reliable detection of air bubbles through both transparent and translucent materials.

Regarding claim 9, Sommer discloses a control means (9) that activates the transmitting means to emit the radiation into the aerosol resting area (inside mouthpiece of Sommer).

Regarding claim 10, Sommer discloses a control means (9) that activates the transmitting means (7) such that first time periods in which the transmitting means emits radiation (infrared light) into the aerosol resting area (inside mouthpiece of Sommer), alternate with second time periods (when not in use) in which the transmitting means (7) does not emit radiation into the aerosol resting area (inside mouthpiece).

Regarding claim 11, when the transmitter (7 of Sommer) is not transmitting light, it is reasonably expected that during this (not in use) second time period the control

means (9 of Sommer) determines the proportion of ambient light in the output signals (as ambient light is the only light being received by the receiver when the transmitter is not transmitting) of the first (20b of Darby) and/or second (20a or Darby) receiving means.

Regarding claim 12, since ambient light is present when the receivers are receiving the infrared light, it is reasonably expected that the control means (9 of Sommer) which receives signals from the receivers, would make use of the proportion of ambient light (the amount of ambient light sensed in combination with the amount of light received by the transmitter) when analyzing the output signals of the first and second receiving means (20b & 20a of Darby).

Regarding claim 13, Sommer discloses a control means (9) that is capable of determining the difference of the output signal of the first receiving means (20b) and the first ambient light proportion (portion of ambient light surrounding 20b prior to the transmitter transmitting infrared light) and/or the difference of the output signal of the second receiving means (20a) and the second ambient light proportion (ambient light surrounding 20a prior to the transmitter transmitting infrared light).

Regarding claim 14, Sommer discloses a control means (9) that is capable of forming a quotient from the difference of the output signal of the second receiving means (20a) and the second ambient light proportion (ambient light surrounding 20a prior to the transmitter transmitting infrared light) and the difference of the output signal of the first receiving means (20b) and the first ambient light proportion (ambient light surrounding 20b prior to the transmitter transmitting infrared light).

Regarding claim 15, Sommer discloses a control means (9) that is capable of forming a quotient from the output signal of the second receiving means (20a) and the output signal of the first receiving means (20b) and it would be obvious to one having ordinary skill in the art to form a quotient in order to determine the signal strength coming from each receiver to the controller.

Regarding claim 16, Sommer discloses infrared light as the radiation emitted by the transmitting means (7).

Regarding claim 17, Sommer discloses a body (5) surrounding the aerosol resting area (inside mouthpiece) that is a mouthpiece (5) for an inhalation therapy device.

Regarding claim 18, Sommer discloses nebulizer devices with a nebulizer nozzle (40 of figure 1) and a membrane nebulizer (52 of figure 12).

Regarding claim 19, Sommer discloses the control means (9) is connected with a compressor (2) for the nebulizer nozzle (40 of figure 1) or with an excitation device (56 of figure 12) for the membrane (52) nebulizer.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. SU 687921 A1; Derwent Accession Number: 1980-H5124C, which is the English Abstract of SU687921A; Platt (4,206,644); Schoeb (2002/0000228); Crouse et al (4,884,065); all of which are drawn to fluid and/or gas delivery systems with inline transmitters and sensors.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771